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**Filed** : March 16, 2001

### **REMARKS**

Claims 1, 14, 30, and 32 has been amended. Claim 33 is added. Claims 1-7, 10-23, and 25-33 are now pending in this application. Claims 15-23, 25-29 and 31 are withdrawn from consideration. Claims 1-7, 10-14, 30 and 32-33 are before the Examiner. The Title has been amended to correspond to the elected invention. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### **Restriction Requirement**

Applicants affirm the election of Group I, claims 1-7 10-14, 30 and 32, without traverse.

#### **Rejection under 35 U.S.C. § 102(b)**

Claims 1-7, 11, 12, 14 and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,471,055 to Opp.

The Examiner asserts that Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration which comprises mixing the test sample with a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde and detecting any visual formation of a second reaction product.

Applicants respectfully submit that Opp does not teach all of the limitations of claim 1 as amended with the Paper of October 17, 2002. Specifically, Opp does not teach that the compound having the amino group and the compound that reacts with the carbonyl group of the aldehyde are contacted with the test sample at the same time. Opp teaches that it may be "desirable to form a layered tablet in which a layer is sandwiched between two layers of a material such as Phthalimide which reduces the amount of the reactant which is exposed at the surface of the tablet. This reduces the extent to which the reactant dissolves instantaneously in the reaction medium." (col. 6, lines 4-10). Opp also teaches two reaction systems that must be separately maintained. (col. 7, lines 5-31). It is further pointed out that in the Examples, the second reactant is always added separately and subsequently to the first reactant. See col. 9, lines

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63-66; col. 10, lines 25-27, 62-64; col. 11, lines 25-27; 61-63; col. 12, lines 28-30, 62-64; and col. 13, lines 26-28, 66-68.

Clearly the method taught by Opp is drawn to a two-step process while Applicants' claimed method requires the presence of the reactants at the same time. Moreover, it is entirely unexpected that different colors can still be determined even when both reactants are present at the same time. Accordingly, the claims are patentably distinct from Opp. As claims 2-7, 11, 12, 14, and 32 contain the limitations of claim 1, these claims are also patentable over Opp.

Furthermore, claim 32 has been amended and claim 33 has been added to describe a preferred embodiment of the invention where the aldehyde is OPA which reacts with a salt of bisulfite in a first reacting step. This claimed combination is favored kinetically and thermodynamically. Support for this amendment is found on page 20, lines 6-8. It is respectfully submitted that this combination is not taught by the cited art.

Other amendments have been made to clarify preferred embodiments. Claim 1 has been amended to clarify that the reaction is carried out in a single container. Support is found, for example, in the Tables (e.g. Table 1) which disclose that the reactions are carried out in vials.

Claim 30 has been amended to recite that the observation of the final color takes place in solution. Support for this amendment is found on page 10, lines 10-11 as well as in Example 1.

Amendments to claim 14 are discussed below.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Opp in view of U.S. Patent No. 4,703,763 to McAlister.

The Examiner asserts that while Opp fail to teach loading a fixed volume of a test sample into a measuring device having a liquid impermeable membrane, McAlister et al. teach a device for sample of a pre-set volume of a test sample. The device includes a plug element which is air-permeable but liquid impermeable. This allows measuring an exact amount of test sample and prevents using excess sample.

In response, while McAlister et al. teach a device that is capable of measuring a pre-set volume, the teaching of McAlister, et al. differs from the claimed invention in that the measuring device does not contain the reactants. In this regard, claim 14 has been amended to clarify that

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both the compound for the first reactant and the compound for the second reactant are contained within the measuring device. This facilitates contacting the compound having an amino group and the compound that reacts with the carbonyl group of the aldehyde with the test sample at the same time as set forth in claim 1, from which claim 14 ultimately depends. As set forth above, Opp teaches two separate reactions which are performed in sequence. Opp does not teach or suggest contacting the compound having an amino group and the compound that reacts with the carbonyl group of the aldehyde with the test sample at the same time. This deficiency is not corrected by McAlister et al. who merely teach a blood sample syringe.

By contacting the test sample with both reactants at the same time, the determination of the point of interest is greatly simplified and faster relative to the two-step process of the prior art. Furthermore, the measuring device of claim 14 provides a tool which is ready for use. There is no need to measure out the reactants. The measuring device can be used immediately to test a sample to determine the point of interest of an aldehyde. The method as presently claimed provides a fast and convenient pass/fail test which is not taught by either of the cited prior art references.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of this ground of rejection is respectfully requested.

Claim 30 is rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,521,376 to Witonsky, et al. in view of U.S. Patent No. 6,436,716 to Wu.

The Examiner asserts that Witonsky et al. teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value by contacting a test sample with a test strip impregnated with a sulfite compounds and an amino acid. Wu is cited for teaching that both sodium sulfite and sodium bisulfite are effective in processes for determining the presence of aldehydes.

In response, Claim 30 has been amended to recite that the presence of an excess of aldehyde is determined "in a test solution to the point of interest by observation of a final color of a test solution." Support for this amendment is found on page 10, lines 10-11 as well as in Example 1. This differs from the teaching of Witonsky et al which teaches the observation of the final color on a test strip.

In order to provide a prima facie case of obviousness, the Patent and Trademark Office has the burden to provide a motivation, teaching or suggestion to create the claimed invention.

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*See, e.g., In re Fine*, 5 U.S.P.Q.2d 1597 (Fed. Cir. 1988). The teaching or suggestion to make the claimed invention must both be found in the prior art, and must not be based on Applicants' disclosure. Such motivation, teaching or suggestion is absent in the references cited by the Examiner for the amended claim.

The disadvantages of a test strip are discussed in the present specification. For example, the specification at page 2, lines 2-10 teaches that the use of a test strip is associated with several problems including: (1) Good solutions (OPA or glutaraldehyde higher than "POI", the point of interest) often fail the test for different reasons; (2) The soaking time and waiting time have to be controlled carefully because any deviation will lead to different shades of color and a false reading; (3) Moving of the strip when soaking will lead to the loss of chemical reagents to the OPA or the glutaraldehyde solutions leading to a false reading; (4) Individual users have different color recognition habits and often have a different opinion of the end-color; and (5) The final color is dependent on many factors and is particularly sensitive to time. Furthermore, the specification at page 10, lines 10-11 teaches that "the solution color is easier to visualize than a test strip paper since the test strip paper itself is colored, leading to false positive results." All of these points illustrate the difficulties associated with accurately reading a test strip. These difficulties are avoided by the presently claimed invention which teaches determining a point of interest in an aldehyde in solution.

In this case, the references cited fail to suggest a method of determining a point of interest of an aldehyde in solution. There is nothing in either Witonsky et al. or Wu that would motivate one of ordinary skill in the art to determine the presence of a point of interest of an aldehyde in a test solution. The teaching of Witonsky et al is drawn to a test strip and Witonsky et al does not identify the problems associated with the use of a test strip described above. Consequently, there is no motivation to modify the teaching of Witonsky et al to an assay that is carried out in solution as presently claimed by Applicants. While Wu provides a teaching that sulfite and bisulfite may be used interchangeably, Wu does not provide motivation to determine the presence of a point of interest of an aldehyde in a test solution. In conclusion, the teaching or motivation to make the claimed invention is not found in the cited art.

In view of Applicants amendments and arguments, reconsideration and withdrawal of this ground of rejection is respectfully requested.

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**CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: \_\_\_\_\_

June 5, 2003

By: \_\_\_\_\_

Che S. Chereskin

Che Swyden Chereskin, Ph.D.

Registration No. 41,466

Agent of Record

Customer No. 20,995

(949) 760-0404

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